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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/636,243	08/10/2000	Bryan S. Wang	8325-0004	6438

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EXAMINER
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WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 04/08/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/636,243	WANG ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 27 December 2002.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 7-19 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 5, 6, 20 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

***Status of Claims***

Claims 1-20 are pending in the application.

Claims 5-6 and 20 are under examination in the application.

Claims 1-4 and 7-19 are withdrawn from consideration as being drawn to the non-elected invention.

***Drawings***

The objection to the drawings have not been obviated simply because applicants have cancelled the reference to Figs. 1-3 in the Examples. Applicants urge that the originally submitted specification contained nine Figures as set forth in the substitute specification. However, because the originally submitted specification referred to more than one Figure by the same reference number (e.g., there were multiple Figure 1s), the Figures were renumbered for clarity in the substitute specification. In response, the original specification (not the substitute specification) contained only two Figures.

Applicants' substitute specification copied the work, in its entirety, of the inventors' published work including the drawings. These drawings were not in the as-filed specification but in the substitute specification. Hence, there is no correspondence between the substitute drawings to any of the description in the as-filed original specification. Rather, the

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original disclosure with only two Drawing Figures corresponded to the current substitute and original as-filed specification, resulting in multiple Figure 1s. See page 9, lines 19-24 which recites for a D-able subsite, corresponding to the as-filed original Figure 1. [The Examples in the specification are normally described with accompanying drawings (Figures), to aid in the understanding of the invention. Applicants' published work (PNAS, 1999) evident the need for the accompanying drawings to describe their work. Note that the drawings and specification of the substitute specification do not find support in the parent provisional application, 60/148,422].

***Information Disclosure Statement***

Applicants acknowledge the consideration of the information disclosure statement (IDS) submitted on 7/9/01. However, as stated in the last Office action, the references listed in the specification (pages 39-40) have not been considered.

***Specification***

The objection to the specification as containing different informalities is maintained in part for reasons stated in the last Office action.

A). Applicants submission of new sequence listing and CRF obviates this objection.

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B). Applicants admit that the as-filed application included manuscripts with their own abstract and background sections. To clarify the confusion applicants submitted their current substitute specification, which contains only one abstract and one background. The current substitute specification eliminated only the headings "abstract" of applicants' manuscripts in PNAS. In response, elimination of the heading, "abstract" does not remove the confusion as to the presence of said abstract in the Examples. In patent application, working examples provided in the specification should admit an illustration of the invention and should not contain a discussion of the general background of the prior art or an abstract. Thus, the incorporation of the entire manuscripts in the Examples is confusing. Cf. with the provisional application of 60/148,422, filed on 8/11/99, which did not include applicants' own work, i.e., the entire manuscripts. The incorporated manuscript did not make any reference to a D-able subsite. Rather, the manuscript discusses a reoptimization of a dimer zinc finger proteins.

C). The objection has been obviated since applicants stated that they have cancelled the hyperlinks.

D). The objection has been obviated with applicants' amendment.

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E). The objection has been obviated with applicants' correction of the minor errors.

F). Applicants urge that the numbers stand for the references cited at the last page of the instant specification. In view of this clarification, the objection is withdrawn.

***Claim Rejections - 35 USC § 112, first paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6 and 20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification does not contain a description of a zinc finger complex comprising of more than two fusion proteins linked via the non-naturally occurring peptide sequences. There is no description in the specification as to the maximum limit of the term "more" than two fusion proteins.

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More importantly, there is no description as to whether the linking of the two linkers result in a stable fusion protein complex containing more than two zinc finger fusion. This is confusing since the Examples do not describe any linking of non-naturally occurring peptide linkers to fuse more than two zinc finger protein of similar sequence. Furthermore, the as-filed specification does not describe a zinc finger protein having the same sequence.

***Claim Rejections - 35 USC § 112, second paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5-6 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendments to the claims obviate the rejection of the claims of record.

The following rejections apply to the newly amended claims:

1. It is not clear as to maximum limit of the fusion peptides included in the claimed "two or more" fusion peptide.

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Claim 5. The metes and bounds of the non-naturally occurring amino acids is not clearly set forth in the specification or claims. Applicants argue that the specification defines said non-natural amino acids. However, it is not the definition that is not at issue. Rather, what is included or excluded by said phrase. The definition that it is not found in nature is obvious. But this does not define what is included or excluded by said phrase.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by Kim et al. (PNAS, 3/98) for reasons advanced in the last Office action.

Applicants argue that Kim contains no disclosure regarding linking two fusion proteins together where each protein contains its own peptide linker.

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Applicants' attention is directed to page 2817, first complete paragraph of the Kim reference. Kim states that "...it is clear that the longer linkers used in our 268/NRE and 268/NRE constructs must relieve some strain that accumulates when a larger set of fingers all are connected with canonical linkers.....four or more fingers are connected via canonical linkers..."

Accordingly, Kim et al fully meets the instantly claimed zinc finger complex.

Claims 5, 6 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by applicants' disclosure referring to Pavletich et al (Science, 1991).

Applicants disclose at page 41, line 32 up to page 42, line 5 that "...we had begun these experiments by adding random 15-residue peptide extension to the N-terminus of fingers one and two of Zif268.... And had used phage display to select fusion proteins that formed stable homodimers on a palindromic DNA site....." Accordingly, the prior art disclosed by applicants fully meets the claimed zinc finger complex wherein each of the zinc finger, Zif (1 and 2) are joined each to a linker.

The rejection of the claims over Eisenberg et al, Choo and Liu are moot in view of the amendments to the claims.

No claim is allowed.

**Conclusion**

This application contains claims 1-4 and 7-19 drawn to an invention nonelected. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T.D. W  
T. D. Wessendorf  
Primary Examiner  
Art Unit 1627

tdw  
April 4, 2003